DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Date: July 11, 2001

From: Hany W. Demian, M.S.
Executive Secretary, Orthopedic and Rehabilitation Devices Advisory Committee
Acting Branch Chief of Orthopaedics Devices Branch

To: Panel Members

Subject: Contents of this Mailing

Panel Members:

This memo is intended to describe the contents of this mailing. This shipment includes:

- **FDA PANEL PACK – YELLOW FOLDER** **All panel members should receive a FDA Panel Pack**

  - **Tab 1:** Device Description and Proposed Indications for Use;
  - **Tab 2:** Executive Summary
  - **Tab 3:** Panel Questions: Panel Members should be prepared to address each panel question at the meeting.
  - **Tab 4:** Pre-Clinical Review Memo, dated July 11, 2001: This memo contains information about:
    1. The History of Device Development;
    2. Device Description;
    3. Device Materials; and
    4. Pre-Clinical Testing.

  - **Tab 5:** Clinical Review Memo, dated July 11, 2001: This memo contains information about:
    1. Clinical Data Development History;
    2. Description of Patients;
    3. Case Series Analysis: (This is the sponsor's analysis presented in Amendments 3 and 5. This is the analysis that will be focused on by FDA and the sponsor at the Panel Meeting.);
    4. Adverse Events Reported in the Case Series Analysis (Amendments 3 and 5) and in the Original PMA. (This information will also be focused on by FDA at the Panel Meeting.);
    5. Summary of Sponsor's Original PMA Clinical Data Analysis;
    6. Summary of Major Deficiencies Identified by FDA in the Original PMA;
    7. Summary of Sponsor's Clinical Data Analysis in Amendment 2;
    8. Summary of Major Deficiencies Identified by FDA in Amendment 2; and
    9. Brief Summary of Literature Information on Alternative Treatments: Information Contained in the Original PMA and Amendment 3.

  - **Tab 6:** Statistical Review Memo, dated July 9, 2001
  - **Tab 7:** Letter dated November 22, 1999 from FDA to Ascension Orthopedics identifying deficiencies for M990022/Module 1 (containing device description, animal testing, and pre-clinical testing information).
  - **Tab 8:** Filing Letter dated February 23, 2001 from FDA to Ascension Orthopedics. In this letter FDA notified Ascension Orthopedics that their PMA would be filed, FDA granted the PMA expedited review for the reasons outlined in the letter, and identified minor deficiencies found up to the time the filing letter was written.
  - **Tab 9:** Letter dated May 1, 2001 from FDA to Ascension Orthopedics identifying major deficiencies for PMA P000057 (Original PMA submission and Amendments 1 and 2).

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- **ASCENSION ORTHOPEDICS' PANEL PACK <u>All panel members should receive a Sponsor Panel Pack</u>**

  - Table of Contents for Information from the PMA provided by the Sponsor. The table of contents identifies the information that is contained in each Module, PMA Volume, and PMA Amendment provided by hardcopy. **<u>All panel members should receive a Table of Contents.</u>**

  - Hard Copy of Sclected Sponsor Information: Each Panel Member Should Receive a Subset of the Following Modules, PMA Volumes, and PMA Amendments.
    - **The Panel Lead Clinical Reviewer should receive 13 Volumes of Sponsor Information.**
    - **The Panel Pre-Clinical Reviewer should receive 13 Volumes of Sponsor Information.**
    - **The Panel Statistician should receive 12 Volumes of Sponsor Information.**
    - **The Industry Representative should receive <u>Only</u> PMA Amendment 3 pp.2-5, 116-121 and Amendment 6 (all pages).**
    - **All of the Panel Members should receive 11 Volumes of Sponsor Information.**
      - Module 1 (Volume 1 of 3)
      - Module 1 (Volume 2 of 3) – **Only for the Panel Pre-Clinical Reviewer**
      - Module 1 (Volume 3 of 3) – **Only for the Panel Lead Clinical Reviewer**
      - PMA (Volume 1 of 13)
      - PMA (Volume 2 of 13)
      - PMA (Volume 3 of 13)
      - PMA (Volume 4 of 13)
      - PMA (Volume 5 of 13) - **Only for the Panel Statistician**
      - PMA (Volume 10 of 13), Appendix 2
      - PMA (Volume 10 of 13), Appendix 3, 4, and 5 – **Only for the Panel Pre-Clinical Reviewer**
      - PMA (Volume 13 of 13) – **Only for the Panel Lead Clinical Reviewer**
      - PMA Amendment 1
      - PMA Amendment 2
      - PMA Amendment 3
      - PMA Amendment 5
      - PMA Amendment 6

  - **<u>CD-ROM</u>** containing all of the information provided by Ascension Orthopedics regarding the Ascension MCP PMA including Module 1 (Volumes 1, 2, and 3), and PMA (Volumes 1-13), and PMA (Amendments 1-6). **<u>All panel members except the Industry Representative should receive a CD-ROM.</u>**

This information is intended to provide you with sufficient details to allow for an objective and focused review of the petition.

If you have any questions regarding the contents of this package or your responsibilities during the panel meeting, please feel free to contact me via either e-mail (<u>hwd@cdrh.fda.gov</u>) or by phone (301-594-2036 extension 184).

Sincerely,

Harry W. Denman, M.S.
Executive Secretary, Orthopedic and Rehabilitation Devices Advisory Committee
Acting Branch Chief of Orthopaedics Devices Branch